UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

In re: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	)	MDL No. 1456 Civil Action No. 01-12257-PBS
THIS DOCUMENT RELATES TO:	)	Subcategory No. 06-11337-PBS
United States of America ex rel. Ven-a-Care of the Florida Keys, Inc. v. Abbott Laboratories, Civil Action No. 06-11337-PBS;	)	Hon. Patti B. Saris
United States of America ex rel. Ven-a-Care of the Florida Keys, Inc. v. Dey, Inc., et al., Civil Action No. 05-11084-PBS; and	)	
United States of America ex rel. Ven-a-Care of the Florida Keys, Inc. v. Boehringer Ingelheim Corp., et al., Civil Action No. 07-10248-PBS	)	

UNITED STATE'S SUR-REPLY IN OPPOSITION TO DEFENDANTS' MOTIONS FOR A FINDING OF SPOLIATION AND FOR SANCTIONS

The second round of defense briefs filed by Abbott, Dey, and Roxane largely fails to address, much less cure, the fundamental defects with their spoliation motions. The defendants cannot establish (1) that any evidence has in fact been spoliated, (2) the legal relevance of the material alleged to have been spoliated, and (3) that the federal Government had a legal duty to preserve evidence in the possession of the states.

I. DEFENDANTS HAVE NOT SHOWN THAT ANY EVIDENCE WAS SPOLIATED

Defendants' spoliation arguments, which focus on whether the Government timely issued preservation directives, proceed from the flawed assumption that absent specific preservation efforts, document destruction at CMS would have occurred as a matter of course. *See, e.g.,* Dkt.

6369 at 9 ("normal procedures for destruction of documents must be suspended"). Absent from defendants' briefs is any indication that it was a "normal procedure" at CMS to destroy documents. In fact, the evidence is to the contrary. Two clear indications that document destruction did not take place at CMS are the extensive productions by the United States in this MDL (*see* Dkt. 6270, at 26-31) and the hundreds of exhibits submitted with defendants' summary judgment briefs - which consist to a large extent of documents generated by the Government.[1/]

Testimony from CMS officials regarding document retention at the agency confirms what is apparent from the record in these cases, that CMS did not destroy documents in the normal course of events. For example, the official in charge of records management at CMS's Office of Strategic Operations and Regulatory Affairs testified as follows.

> Q. Who sends you the notice that documents are scheduled for destruction?
>
> A. I have never received such a notice.
>
> Q. Maybe I misunderstood your testimony.
>
> A. Right. I was explaining what the process would be. But I'm saying that we are not there yet. We haven't destroyed any records. And, furthermore, any documents that go to the federal record center are permanent records, so they would never be destroyed. After they are maintained at the federal record center for 20 years, then they go to the national archives.
>
> Q. That's for all records that come out of –
>
> A. For permanent records.
>
> Q. For permanent records only. If they are not permanent records though they have a different –
>
> A. Yes.

[1/] *See* Dkt. 6184, Exs.1- 296 (by Dey); Dkt. 6201, Exs. 1-219 (by Roxane); Dkt. 6188, Exs. A - FQ (by Abbott); Dkt. 6456, Exs. 1-140 (by Abbott); Dkt. 6449, Exs. 1-215 (common); Dkt. 6426, Exs. 297-418 (by Dey); Dkt. 6427, Exs. 220-335 (by Roxane); Dkt. 6566, Exs. A-E (common); Dkt. 6571, Exs. A-B (by Abbott); Dkt. 6617, Exs. 336-340 (by Roxane).

Q. – production or retention –

A. Retention, yes. That's correct.

Q. Schedule? So you have only been talking about permanent records with respect to the non-destruction of documents?

A. I'm saying that we never destroy any documents, temporary or otherwise.

Q. Okay. And is that according to a written policy of CMS?

A. Well, as I was trying to explain, in 2004 when we changed our record schedule, we provided for a shorter retention period for temporary records. And we are not yet to the place in the process or we haven't yet developed, we haven't started destroying temporary records yet.

Q. So although the policy calls for the destruction, you haven't destroyed any?

A. Right. Not yet. Not yet. And if – when we get there, if there are any that need to be preserved under a preservation order, then I would ensure that they were preserved.

June 6, 2007 Trans. of L. Parker at 64:4-65:22 (Ex. 1 (attached)). This testimony is consistent with that of that of high-level CMS officials, such as the former Associate Administrator for Policy, who had substantive responsibility in the drug reimbursement area during the claims period in these cases. Sept. 12, 2007 Trans. of K. Buto at 97:2-98:20 (Ex. 2 (attached)).

With respect to the alleged spoliation of materials by the states, the centerpiece of defendants' motion is a 2006 e-mail from a New York official who expressed frustration with the discovery burdens attendant to the AWP litigation. As previously noted, from the entire text of the email, it readily appears that New York state personnel have taken their production obligations in the AWP litigation seriously and felt the burden of those responsibilities. Defendants further attempt to make hay with the fact that the New York email had not, as of the filing of defendants' spoliation briefs, been produced by any state other than Georgia. According to defendants, "the absence of this email in the productions of other states speaks for itself." Dkt. 6369 at 11.

The inference sought to be drawn here by defendants makes no sense, however, even looking at the production obligations of New York. Under the CMO in the New York Counties case, the cut-off date for discovery purposes is *2005.* Dkt. 4745, ¶¶ 5, 7. Upon specific information and belief, the scope of production with respect to the third-party subpoena served by MDL defendants on the State of New York also did not extend past 2005. In short, neither New York State, nor the New York Counties, were under any obligation to produce an email from 2006.

The sparse record here simply does not support a finding of spoliation with respect to New York, much less across 50 states as alleged by defendants. Most tellingly, there has been no direct finding of spoliation against New York or any other state except Nevada, in this MDL or in the cases pending around the country. In fact, many states have now gone to trial with a record deemed sufficient to adjudicate liability against various drug manufacturers. Accordingly, defendants' spoliation allegations against the United States appear to be a back-door attempt to obtain a broad ruling about state document destruction in the absence of any direct finding of spoliation against the states which actually had possession of the material in question.

II. DEFENDANTS HAVE NOT ESTABLISHED THE RELEVANCE OF ANY PURPORTEDLY SPOLIATED EVIDENCE

In its oppositions to defendants' spoliation briefs, the Government demonstrated, *inter alia*, that defendants' allegations concern categories of material that are not relevant to the claims and defenses actually pled in this case, and that defendants failed to establish the relevance of specific categories of purportedly spoliated evidence under any legal theory. In reply, defendants cite principally to this Court's 2008 Memorandum and Order resolving cross-motions for summary judgment in the AWP/WAC case brought by the Commonwealth of Massachusetts (*Commonwealth of Mass. v. Mylan,* 608 F. Supp. 2d 127 (D. Mass. 2008)) and to comments by the Court during a hearing on July 8, 2009 involving the lawsuits by the New York Counties. As will

be explained in a later section of this brief, neither the cited decision nor the hearing transcript provide support for defendants' arguments.

Of much greater significance, however, to the Court's evaluation of the spoliation motions is the recent decision of the First Circuit affirming both the seminal November 2006 holding by this Court in the AWP MDL and the judgement entered against AstraZeneca Pharmaceuticals in June 2007. Accordingly, the more fundamental task now at hand is to assess the relevancy of purportedly spoliated evidence in light of the First Circuit's decision, as well as additional case law from this and other circuits which set out the legal principles which will be used to determine whether defendants knowingly reported or caused to be reported false Average Wholesale Prices (AWPs). Finally, defendants have still failed to explain how evidence which they have never seen, whether it was spoliated or not, could have affected their scienter during the claims periods in these cases.

A. The Falsity of Published AWPs for Defendants' Drugs Will be Determined as a Matter of Law - Not by Reference to Non-Public, Internal Agency Documents

In the intervened *qui tam* cases, the Government alleges that (1) defendants reported false prices which (2) caused Medicare and Medicaid claims to be paid at inflated amounts, and (3) defendants had "knowledge" of the falsity of the reported prices. At this point, it is clear from prior decisions by this Court in the MDL, the First Circuit's September 2009 decision, as well as precedent from other Circuits, that the issue of falsity should be decided as a matter of law given that there is no factual dispute about the amount of defendants' reported prices. Similarly, the issue of causation (or materiality) can and should be decided on the current record. Defendants have not identified a piece, or even a category, of evidence that would affect the Court's assessment of whether their reported prices are false based on the legal principles that govern the

the causes of action actually pled by the United States in these False Claims Act (FCA) cases. In short, the fundamental question asked by the Court at the outset of the case regarding purportedly missing evidence ("What would you have found?), remains unanswered by defendants even after the close of discovery and with trial just months away.

What is clear on the record here is that Medicare and Medicaid drug payment policies - which expressly limit the amount that should have been paid by the federal Government for drugs – are creatures of federal statute and regulation. The Court's holding that the operative term in the Medicare regulation – AWP – shall be construed pursuant to its plain language has been affirmed. *In re Pharm. Indus. Average Wholesale Price Litig.*, 582 F.3d 156, 168-72 (1st Cir. 2009). The upper payment limit under Medicaid for the drugs at issue in these cases is Estimated Acquisition Cost or EAC. *Massachusetts v. Mylan,* 608 F. Supp. 2d at 132. As was the case with the term "AWP," the meaning of the term "EAC" will be resolved as a legal question - to the extent there is one, which seems unlikely given that the term is expressly defined in the regulations. *See id.* (quoting 42 C.F.R. § 447.301 which defines EAC as "the agency's best estimate of the price generally and currently paid by providers for a drug marketed or sold by a particular manufacturer....").

Whether defendants' reported prices for the drugs at issue are false should be resolved as a legal question under federal law. *United States ex rel. Oliver v. Parsons Co.,* 195 F.3d 457, 463 (9th Cir. 1999) (the "meaning [of Federal regulations] is ultimately the subject of judicial interpretation, and it is [defendant's] compliance with [the] regulations, as interpreted by the court, that determines whether its [conduct] resulted in the submission of false claims under the [FCA]"). Defendants' arguments that some purported interest on the part of states to pay for drugs at amounts which vastly exceed EAC trumps a federal regulation which expressly caps such

payments at EAC are legally unavailing. *See, e.g., Independent Living Ctr. So. Cal. v. Maxwell-Jolly*, 572 F.3d. 644, 653 (9th Cir. 2009) (enjoining payment rates established under state plan which conflicted with federal Medicaid statute based on doctrine of conflict preemption); *City of N.Y. v. Federal Commc'ns Comm'n.,* 486 U.S. 57, 64 (1988) ("regulations of [a federal] agency will pre-empt any state or local law that conflicts with such regulations or frustrates the purposes thereof").

At this point in the MDL, every conceivable argument that applicable law permitted (or, according to Abbott, even encouraged) the reporting of inflated prices has been laid to rest by prior opinions by this Court and the September 2009 decision of the First Circuit. For example, with respect to the argument that "Congress and the relevant regulators were aware of ... industry usage [of the term "AWP"] and . . . adopted it for purposes of the BBA" [Balanced Budget Act], the First Circuit could not have been more explicit in rejecting this argument, stating simply: "We disagree." *In re Pharm. Indus. Average Wholesale Price Litig.*, 582 F.3d at 163. The Court of Appeals further agreed with the District Court that a finding that Congress intended to use AWP as a term of art would lead to the "absurd outcome of giving the pharmaceutical industry 'free reign over drug pricing'" and allow the posting of "AWPs without any connection to prices in the market." *Id.* at 170, n. 9. Rather, the First Circuit read "the legislative history and statutory context to be one of slow adaptation to shadowy industry practices, not ratification of them." *Id.* at 171.

Moreover, determination of the intent behind federal regulations (where the inquiry is not resolved by the plain language) is by reference only to the official *public* record. *United States v. Lachman*, 387 F.3d 42, 54 (1st Cir. 2004), *cited in In re Pharm. Indus. Average Wholesale Price Litig.*, 582 F.3d at 167-68. Consistent with the principles set out in *Lachman*, the Court of

Appeals, much as this Court did in the November 2006 AWP ruling, reviewed the official public record[2/] in reaching its own, *de novo*, conclusion about the meaning of the term AWP. *Id.* at 163-167.

As with Medicare, Medicaid payment limits will be determined by reference to federal law. There is no reason to believe that the Court of Appeals would conclude that Medicaid operates with fundamentally different cost control objectives than Medicare. With respect to Medicare, the First Circuit held that there is no basis to find "that Congress was supportive of . . . a scheme whereby the AWP represented a sticker price bearing no relation to actual acquisition costs, thereby leaving Medicare and its beneficiaries to pay vast multiples above what physicians paid for the drugs in question." *Id.* at 171. The same conclusion should apply in the context of Medicaid, especially given the EAC limit established by federal regulation.

In sum, federal policy with respect to both Medicare and Medicaid is determined, first, based on statutes and regulations and, where inquiry goes beyond the plain language of the laws, by reference to official agency promulgations, not internal, non-public documents – spoliated or otherwise.

[2/] For example, the Court of Appeals looked to (a) the language of pertinent statutes, including 42 U.S.C. §§1395*l*(a), 1395u(b), 1395u(*o*), 1395w-3, 1395w-3a, 1395w-3b, 4556(c) (*In re Pharm. Industry AWP Litig.*, 582 F.3d at 164, 165, 167), the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, Pub.L. 106-554 § 429(c), 114 Stat. 2763 (*id.* at 166); (b) statements in the official legislative history for federal statutes, including those in H.R.Rep. No. 105-149 (1997), H.R.Rep. No. 108-178 (2003); (c) Federal regulations, including 42 C.F.R. §§ 405.500 *et seq.* (*id.* at 164); and (d) Federal Register notices of proposed and final agency rulemakings, including those published at 56 Fed. Reg. 59,502 (Nov. 25, 1991), 56 Fed. Reg. 25,792 (June 5, 1991), 63 Fed. Reg. 58,814 (Nov. 2, 2003) (*id.* at 164, 165, 166).

B. Documents Which Defendants Have Never Seen are Irrelevant to Scienter

In opposing defendants' spoliation motions, the Government argued that documents in the files of CMS or OIG which defendants have never seen, irrespective of whether they were preserved, are irrelevant to the determination of whether defendants "knowingly" reported false prices to the AWP compendia. Further, the weight of authority holds that government approval regarding a false claim or statement is relevant only to whether a defendant made a "knowing misrepresentation." *See Massachusetts v. Mylan Labs.,* 608 F. Supp. 2d at 149 (quoting *United States v. Newport News Shipbuilding Inc.*, 276 F. Supp. 2d 539, 564 (E.D. Va. 2003)); *see also In re Pharm. Industry AWP Litig*., 254 F.R.D. 35, 42 (D. Mass. 2008). The appropriate "focus of the [government approval] defense is not on what the Government knew; rather the defense focuses on whether the defendant acted knowingly, examining the effect of the Government's knowledge on the defendant." Michael J. Davidson, *The Government Knowledge Defense to the Civil False Claims Act: A Misnomer by Any Other Name Does Not Sound as Sweet*, 45 Idaho L. Rev. 41, 56 (2008).

Rather than addressing this key element of the relevancy issue, defendants simply ignore it. Yet resolution of the legal issue of whether and/or how the Government's knowledge of inflated AWPs is relevant to defendants' FCA liability is fundamental to both the dispositive motions that have now been fully briefed, as well as the spoliation motions.

C. Defendants' Relevancy Arguments Lack Support

1. The Case Law Cited By Defendants Is Not on Point

Defendants rely on *Gagne v. Reddy*, 104 F.R.D. 454 (D. Mass. 1984), for the proposition that "relevancy is broadly construed at the discovery stage of litigation..." Fact discovery in the Government's FCA cases,however, closed over a year and half ago, briefing on dispositive

motions was completed months ago, and the trial date set by the Court is just months away. The Court is well-positioned to make legal decisions regarding the relevancy of the "government approval" evidence proffered by defendants in connection with the summary judgment briefs, as well as the supposedly spoliated evidence of such approval. Assertions about the appropriate scope of fact discovery at this point are useless.

Defendants' reliance on a single sentence from this Court's Memorandum and Order in the Massachusetts case, *Massachusetts v. Mylan,* 608 F.Supp.2d at 152 ("[w]ith respect to the post - 2002 period, a Government knowledge defense is viable because the government decided to continue using WAC's as a policy matter") is similarly unavailing. According to defendants, "DOJ's position on relevance would have blocked all this evidence from consideration." Dkt. 6369, at 16. Defendants ignore, however, that the Court based this statement on a definition in Massachusetts's *regulations*[3/] - not on some internal, non-public state document. *See Massachusetts v. Mylan,* 608 F. Supp. 2d at 132-34 (noting that, effective April 1, 2003, state regulation defined WAC as "a manufacturer's price published in a national price compendium ...."). In any event, the decision in the Mylan case related, *inter alia*, to whether Massachusetts's reliance on published prices was reasonable, in the context of the Commonwealth's common law fraud claims. Accordingly, and as noted by the Court during a hearing on October 20, 2009, the part of that decision dealing with reliance by the state has no application in these FCA cases where the federal Government has dismissed its common law fraud claims.

Defendants' relevance arguments continue to fundamentally misunderstand how the Government establishes payment policy. There is simply no First Circuit precedent (or from any

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[3/] *See* 130 Mass. Code Regs. 406.402; 970 Mass. Reg. 57 (Mar. 28, 2003, effective Apr. 1. 2003) *cited in* Par's Statement of Facts, ¶ 33 (Dkt. 456 in C.A. 03-11865-PBS).

other circuit) for the proposition that federal regulations, after promulgation via notice and comment rulemaking in accordance with the Administrative Procedure Act, are subject to constructive amendment by the Government's purported "acquiescence" in the abuse of a government program. *Accord, In re Pharm. Indus. Average Wholesale Price Litig.*, 582 F.3d at 171, n. 10 (agreeing that the fact that "opportunities for abuse exist in the Medicare statute does not mean that Congress has authorized them").

2. The Legal Question Raised by the Court in the New York Counties Case Should Now be Resolved

At a July 2009 tutorial in the New York Counties case, the Court noted that the Government's access to AMP information "fairly teed-up" the "government knowledge defense." July 8, 2009 Hrg. at 77. The Court then stated a rhetorical question: "I think they felt they [CMS analysts] couldn't look at them [AMPs] because they weren't published prices, but they could have gotten access if they wanted to. The question is, is that enough to trigger a government-knowledge defense?" *Id*. at 79.

First, these cases are now at a juncture where the legal question posed by the Court should be resolved. Second, the answer to the question is "no." Prior to passage of the Medicare Modernization Act of 2003 ("MMA"), government policy for both Medicare and Medicaid was to use pricing points other than AMPs (*i.e.*, AWPs or WACs) to determine payment amounts in the first instance, as well as to set Federal Upper Limits, or "FULs" (which was the context in which the Court made the comment quoted above). There is no precedent in the FCA for the extraordinary proposition that the Government is somehow disabled when seeking redress for fraud or abuse because it refrained from abandoning one payment methodology and implementing a different one possibly less prone to abuse. The Government's hypothetical ability to adopt methodologies other than the ones actually in place - with respect to estimating the ingredient cost

of a drug or setting a FUL – is simply irrelevant. Nor is there any precedent for the proposition that the Medicare and Medicaid programs, which were processing millions of drug claims a month, should have abandoned the overarching payment methodologies on an *ad hoc,* manufacturer or drug-specific, basis as evidence

Finally, at bottom, defendants are asserting that evidence of the Government's time-consuming and costly attempts to understand and respond to the very abuse which is the subject of this MDL actually provides a defense to the liability pled in the Government's FCA cases – and that they have been prejudiced by the alleged spoliation of additional, yet unspecified, evidence which might relate to the Government's efforts grapple with AWP inflation. The extensive record does not establish approval of AWP manipulation, but rather shows the extent of the broad harm caused by the AWP abuse at issue here. Any such evidence is not exculpatory and is irrelevant to the issue of the falsity of defendants' published AWPs.

The harm to the Government from AWP inflation was two-fold. First, AWP manipulation caused the Medicare and Medicaid programs to pay provider and supplier claims at inflated amounts. The United States has submitted expert reports which calculate the monetary harm based on drugs claims actually paid. The second harm from defendants' conduct relates to the Government's efforts to analyze and craft policies responsive to AWP abuse during the 1990s and into the next decade. The cost to the Government associated with the second type of harm has not been calculated or pled – but is manifest nonetheless.

As recognized by the Court, HHS's Office of Inspector General devoted considerable resources in its attempt to understand the costs actually being incurred by providers and suppliers when obtaining drugs covered by Medicare and Medicaid. *In re Pharm. Industry AWP Litig.*, 491 F.Supp.2d 20, 41-44 (D. Mass. 2007). Absent that abuse, determination of the real acquisition

costs of drugs would have been a simple, inexpensive exercise – one could have simply consulted the compendia to obtain the information. Defendants argue that they have somehow been prejudiced by the purported spoliation of documents in OIG work paper files. That claim, in addition to lacking a factual basis, is extravagant given that the underlying OIG material is more appropriately seen as evidence of resources consumed and costs incurred by the United States as a direct result of AWP abuse by defendants.

Material relating to other government efforts to contend with AWP inflation are no more availing to defendants. For example, in 2000, CMS issued a Program Memorandum advising Medicare Carriers that they could use information compiled by the Department of Justice and the National Association of Medicaid Fraud Control Units as an alternative source of AWPs. Again, the considerable and costly efforts by the Government to develop information about real prices and provide it to the victim agency stemmed directly from the AWP abuse by drug manufacturers which had rendered information in the price compendia unreliable with respect to an unknown number of drugs.

In a similar vein, defendants point to an agency decision memorandum from 2002 which describes CMS's efforts to reassess the standards used to evaluate Medicaid State Plan Amendments submitted by states. *See* Dkt. 6369, Ex. BB. The memorandum explains that Medicaid regulations define a drug "ingredient cost" as the state "agency's best estimate of the price generally and currently paid by providers for" the drug. The memorandum then discusses OIG's reports which found that actual acquisition costs were below published AWPs and sets out the problem created by this situation: "It is increasingly difficult to require states to provide statistical data to support their proposed rates...." The memorandum then lays out options for dealing with this problem.

The problem which confronted the agency is precisely the same abuse at issue here. Again, absent AWP inflation, approval of State Plan Amendments covering drug payment methodologies would have been much simpler. As noted in the memorandum, the principal criterion in the regulations is whether a state's methodology will result in payment amounts that correspond to the costs generally and currently incurred by providers. Pricing compendia should have provided a readily accessible and relatively inexpensive reference for both CMS and states to verify that a proposed payment methodology conformed to regulatory requirements.

III. THE OBLIGATION TO PRESERVE EVIDENCE EXTENDS NO FURTHER THAN THE OBLIGATION TO PRODUCE IT

The United States previously argued that the scope of the duty to preserve evidence should be coextensive with the scope of the duty to produce documents, *i.e.*, it is limited to documents in the possession, custody, or control of the party. *See* Dkt. 6388 at 9-11 (and authorities cited therein). This position is consistent with that stated by the Court regarding discovery of state claims data. *See* Trans. of Nov. 13, 2008, at 45 ("I tell you what, if you [defendants] want to subpoena it [state-level claims data], subpoena it."). Indeed, the Court amended the Case Management Order and extended the close of fact discovery specifically to allow the parties to conduct discovery of the states. *See* Order of Oct. 6, 2008 (docket entry).

Defendants cannot establish a preservation and production obligation on the part of the federal Government with respect to state material. For example, defendants' reliance on *Rosie D. v. Romney*, 256 F. Supp. 2d 115 (D. Mass. 2003) is misplaced. That decision held only that state Medicaid officials were required to produce Medicaid documents from managed care organizations used by the state's Division of Medical Assistance to administer services. 256 F. Supp. 2d at 119. As used by Massachusetts, these organizations seem facially similar to the Carriers and DMERCs which administer Medicare payments for CMS. The United States in these cases accepted

responsibility to produce materials held by the Carriers and DMERCs. There is no basis to find that the states' relationship with CMS is in any way similar to the relationship between the agency and the private contractors, such as the Carriers and DMERCs, which are paid to administer payments for the Medicare program – entities which have been described as "agents" of CMS based on their contracts with the agency.

Cases finding a preservation duty with respect to materials held by a principal's agent are also cited by defendants in support of the contention that CMS had "control" of state documents. *See* Dkt. 6605, at 9 (citing *McKesson Corp. v. Islamic Rep. of Iran*, 185 F.R.D. 70 (D.D.C. 1999)). It does not, however, appear that States have ever been described as "agents" of the federal Government in connection with the Medicaid program, and defendants have not proffered any argument or authority in support of this very novel proposition.

Defendants' attempt to establish that CMS had control of state documents by virtue of statutory provisions similarly fails to withstand scrutiny. The provisions of the Social Security Act cited by defendants, 42 U.S.C. § 1396a(a)(6), (42), and (69), in support of this argument are not on point. The three provisions cited by defendants state as follows:

> A State plan for medical assistance must -
>
> * * * * * *
>
> (6) provide that the State agency will make such reports, in such form and containing such information, as the Secretary may from time to time require, and comply with such provisions as the Secretary may from time to time find necessary to assure the correctness and verification of such reports.
>
> * * * * * *
>
> (42) provide that the records of any entity participating in the plan and providing services reimbursable on a cost-related basis will be audited as the Secretary determines to be necessary to insure that proper payments are made under the plan;
>
> * * * * * *
>
> (69) provide that the State must comply with any requirements determined by the Secretary to be necessary for carrying out the Medicaid Integrity Program established under section 1396u-6 of this title...

Defendants have not explained how any of these provisions gives CMS authority to issue litigation preservation directives to state agencies. The sections, on their face, do not establish such authority. For example, subsection 42 is completely off point in that it concerns audits of entities reimbursed on a cost-related basis, and therefore plainly has no application in these cases.

In sum, there is no basis in the federal rules, statutes, or case law to support a holding that the United States was under an obligation to preserve and produce material in the possession of other sovereigns. The United States respectfully suggests that the Court refrain from adopting such a radical expansion of the Government's preservation and production obligations in these cases.

IV. CONCLUSION

Defendants have asked the Court to find that the Government failed to preserve evidence and that the purportedly spoliated material is "critical" to this case. The United State's responsive briefs, as well as the entire record in these cases, amply demonstrate that neither assertion is true. Pursuant to long-standing retention policies and specific directives concerning this MDL, Government agencies both preserved and produced extensive material relating to the subject matter of this case. Furthermore, defendants' arguments regarding the legal relevancy of the material alleged to have been spoliated are meritless. Ultimately, *the liability of defendants* in these cases will be determined based on evidence relating to *the conduct of the defendants* – not on the baseless evidentiary presumptions requested by defendants as sanctions against the United States.

Respectfully submitted,

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Dated: December 4, 2009

I hereby certify that I have this day caused an electronic copy of the above **SUR-REPLY IN OPPOSITION TO DEFENDANTS' MOTIONS FOR A FINDING OF SPOLIATION AND FOR SANCTIONS** to be served on all counsel of record via electronic service pursuant to Paragraph 11 of Case Management Order No. 2 by sending a copy to LexisNexis File & Serve for posting and notification to all parties.

/s/ Justin Draycott

Dated: December 4, 2009 Justin Draycott